Plaque Modification: A Review of Current Strategies.

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Objectives

To understand the variety of plaque modification devices available in order to diminish issues arising from chronically hardened atherosclerotic lesions. Also, to understand possible complications and limitations of these strategies in addition to knowing some of the data related to these devices.

Background

Endovascular management of peripheral arterial disease continues to evolve. These changes are addressing challenges that are hindering optimal outcomes for patients. One of these challenges is chronically hardened lesions that are typically calcified. These lesions result in a variety of technical issues including impaired device delivery, decreased luminal revascularization, impaired stent expansion, increased risk of in-stent stenosis and thrombosis, increased procedural time, cost, and overall radiation dose. For this reason, plaque modification devices have been developed to mitigate this issue. This presentation will describe these strategies and provide the reader with an overview of devices that can be used to treat chronically hardened lesions.

Pre-Treatment Strategies

Conventional Balloon Angioplasty:
Plain old or conventional angioplasty can be seen as the original plaque modification strategy. These balloons can be compliant, non-compliant or semi-compliant. They allow for predilation of the lesion which can then be treated with a stent or drug coated balloon. Advantages include cheap cost, wide selection of available balloon diameters and lengths, delivery shaft lengths, different wire size compatibility, and options for rapid exchange. There are obvious limitations to using conventional balloons, especially in chronically hardened lesions. The more hardened the lesions, the more likely there will be elastic recoil with use of a plain old angioplasty. These balloons tend to under dilate when treating the most calcified segments resulting in suboptimal target lesion response. High pressure, non-compliant balloons may improve target lesion response, but can increase the risk of vessel rupture. Conventional angioplasty balloons traditionally have a single layer structure and are prone to rupture when treating heavily calcified lesions. In addition, they are not free from other well-known complications such as dissections and perforations[1].

High Pressure Non-Compliant Balloons:
Given the above limitations, balloons with a double layer that are non-compliant and allow for high pressures have been developed. Examples of these include the Dorado (Bard, New Jersey), Conquest (Bard, New Jersey), Jade (OrbusNeich, Hong Kong) and OPN (SIS Medical, Switzerland) balloons. They can reach pressures up to 35 to 40 atm. They allow for uniform dilation within the lesion, which is especially useful in the calcified segments. High radial forces are applied to the hardened wall without sacrificing uniform dilation of the lesion. In addition, the balloon itself is less likely to rupture given their dual layer construction which is especially useful when modifying spiculated calcifications[2]. One limitation to these balloons is that they should be used in caution given their high pressure, non-compliance, and dual layer nature. Applying exceedingly high pressures and radial forces in a calcified segment can result in vessel dissection or possibly perforation requiring emergent treatment. Even if the lesion is not dissected or perforated, the injury induced on the vessel wall can lead to higher rates of future restenosis regardless of the final treatment modality used[3].

Cutting Balloons:
Understanding that high pressure balloons can lead to excessive vessel wall injury, balloons with implanted metallic crosspieces or struts have been designed. Cutting balloons are one example of this and are non-compliant angioplasty balloons consisting of 3 to 4 longitudinal blades placed along the exterior of the balloon (Figure 1). The balloon is used at low pressures (around 6-8 atm) with the blades along the surface of the balloon, applying a force that is linearly concentrated. This in turn creates superficial incisions within the plaque which leads to improved vessel compliance. With improved compliance, the vessel can better accept conventional or drug-coated angioplasty and stents with less likelihood for early restenosis. Due to requiring less force to dilate the lesion, cutting balloons are believed to cause less vessel trauma[4]. Cutting balloons can also be used for in-stent restenosis, bypass grafts, and dialysis access work[5,6]. Examples of cutting balloons are the Peripheral Cutting Balloon (PCB), Flextome, and Wolverine (Boston Scientific, Marlborough, MA). Inflated pressures with cutting balloons should be kept low. Too high of pressures may overly incise the vessel wall and lead to greater inflammation within the wall, thus leading to earlier restenosis. Inflating too aggressively can also bring about the risks of dissection and perforation. Per manufacturer recommendation, dilation and deflation should be slowly performed and the balloon should be fully deflated before removal. Quick and partial deflations can result in the blades being dislodged[7].

Figure 1. Wolverine© cutting balloon with the longitudinal blades. This iteration is more easily deliverable and requires 5 and 6 French sheaths.*

Scoring Balloons:
Due to the trauma induced by cutting balloons in addition to difficult delivery, scoring balloons were developed. Instead of having longitudinal blades, the scoring balloon is semi-compliant and has 3 to 4 nitinol struts that are helically arranged about the balloon (Figure 2). This design, in theory, is supposed to reduce vessel wall injury but also provide focused radial pressure in order to improve vessel wall compliance. Examples of scoring balloons include the Lacrosse NSE (Asomedica, Belarus) and Angiosculpt (Phillips, Netherlands). Although the above issues listed with cutting balloons should be less with the design of the scoring balloons, caution should be taken with over inflation[8].

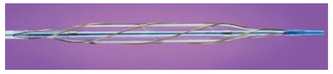


Figure 2. Image of the Angiosculpt© scoring balloon with the struts helically arranged around the balloon.

Chocolate Balloon
The Chocolate Balloon (TriReme Medical, Pleasanton, CA) consists of a balloon that is circumferentially divided by nitinol struts. When inflated, the balloon will have multiple indentations and gorges (Figure 3). These indentations and gorges will increase the surface area of the balloon on the vessel wall and will allow for the force applied by the balloon on the vessel wall to be dispersed over a greater surface area. With the force dispersed over a greater surface area, it is theorized that the chances of arterial wall injury will decrease[9]. Per manufacturer recommendation, the Chocolate balloon should be inflated to half nominal within 30 seconds then to slowly inflate to nominal over another 90 seconds. The balloon should be sized at a 1:1 ratio with the treated vessel. Also now available is a Chocolate Balloon that is coated with paclitaxel (Chocolate Touch Balloon)[9].

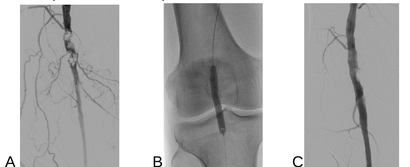
Figure 3. Chocolate© angioplasty balloon emphasizing the indentations within the balloon

Serration Balloon
This balloon consists of serrated struts that are arranged longitudinally along the balloon. The serrated struts are what differentiate these balloons from scoring balloons that have uniform struts (Figure 4). With the serrated struts, focal force is applied to the calcified vessel wall but at more defined points when compared to cutting and scoring balloons. This can be thought of as interrupted scoring. The Serranator Balloon (Cagent Vascular, Wayne PA) is the only type currently on the market. This balloon is semi-compliant and requires a 6 French sheath and goes over an 018 wire. Like the cutting and scoring balloons, low pressure should be utilized with a nominal pressure of 6 atm. Device lengths and diameters are limited for this balloon[10].

Figure 4. Serranator© angioplasty balloon with a demonstration of its serrated struts.

Intravascular Lithotripsy:
This balloon vaporizes a fluid mixture of saline and contrast within the balloon to create sonic pressure waves, currently only commercially available as the Shockwave catheter (Shockwave Medical, Santa Clara CA). The energy carried by these high-amplitude pressure waves cause microfractures within high density structures such as calcified vessels leading to improved vessel compliance (Image 1). This technology has been used for years in urologic interventions for stone treatment[11]. Shockwave is a low-pressure balloon and is supposed to induce less trauma and inflammation on the vessel when compared to conventional angioplasty, cutting, or sculpting balloons due to the lack of significant mechanical force/expansion. This in turn, theoretically decreases issues related to arterial wall injury such as restenosis and complications such as dissection and perforation. Due to Shockwave working by converting electrical energy into sound energy, the balloon can induce cardiac rhythm changes, although these have not shown patient harm. Shockwave emits the most energy at the most distal and proximal emitters, the operator should be aware balloon positioning if there is a medium or long length calcified lesion. Due to the balloon emitting energy in a circumferential fashion, there is some concern that efficacy may be limited with non-circumferentially calcified lesions and be prone to balloon rupture with spiculated calcifications. The balloon should be in apposition against the wall for optimal use[11]. Finally, it should be noted that the number of pulses emitted per device is limited and once those pulses are used, the balloon essentially becomes a low-pressure conventional balloon.

Image 1. 71 year old male presented with ischemic rest pain. A. Digital subtraction image demonstrates a calcified occlusion of the popliteal artery. B. This was treated with a 6.5 x 60 mm Shockwave© balloon. C. Digital subtraction image after the 6.5mm intravascular lithotripsy demonstrates improved luminal patency. Given that a less than 30% stenosis focally remained, no further treatment was performed after the 6.5mm intravascular lithotripsy.



Cryoplasty:
Cryoplasty uses a low-pressure balloon to apply cryotherapy to the target vessel. Cryotherapy consists of -10 C applied to the vessel wall over 30 seconds. The cryotherapy is thought to improve vessel compliance by breaking down collagen fibrils and induce apoptosis of the smooth muscle cells within the vessel walls[12]. There are concerns regarding the cost of cryoplasty regarding how effective it is compared to conventional angioplasty. In the prospective randomized single center study performed by Spiliopoulos et al., that compared cryoplasty to conventional angioplasty in diabetic femoropopliteal lesions, cryoplasty was less effective than conventional angioplasty[13]. The CLIMB study showed similar outcomes between cryoplasty and conventional angioplasty for infrapopliteal vessels[14]. Thus, clinical benefit of using cryoplasty remains in doubt.

Atherectomy:
There are a variety of atherectomy devices available that employ a variety of means to debulk vessel plaque and calcifications (Image 2). Using atherectomy only for vessel prep or for both vessel prep and final vessel treatment is debatable. Data comparing atherectomy against angioplasty and stenting has yet to demonstrate a clear benefit of using atherectomy, especially in lieu of the cost associated with atherectomy. In a retrospective analysis of tibial interventions that had angioplasty alone or laser, orbital, and directional atherectomy with angioplasty, no benefit was seen with the use of atherectomy[15]. Evaluation of the Vascular Quality Initiative registry from 2010 to 2015 that involved 16,838 patients demonstrated high risk of amputation and adverse events with atherectomy when compared to angioplasty or stenting[16]. A Cochrane Library metanalysis did not find a benefit of atherectomy over plain old angioplasty with and without stenting. The only benefit this metanalysis found was possibly decreased dissection and bailout stenting[17]. Atherectomy as a final treatment option could be considered in patients who would like to avoid placement of permanent stents or where stents may not do well such as in muscular flexion points [18,19]. When performing atherectomy, true lumen recanalization should be ensured given risk of complications in performing atherectomy in a subintimal space[20]. In addition, risk of emboli is increased with use of atherectomy devices and should be considered prior to use.

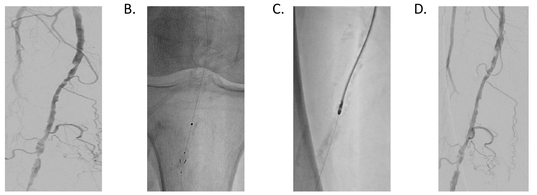
Rotational Atherectomy:
Rotational atherectomy involves having an elliptical burr on a catheter tip that is diamond covered and rotates at high speeds. An example is the Phoenix device (Phillips, Netherlands). If the burr is on the side of the catheter, it is referred to as directional atherectomy such as with the Silverhawk, TurboHawk, and HawkOne (Figure 5) devices (Medtronic, Ireland)[2]. Whether the burr is on the side or tip, at high speeds the burr can cut fibrous and calcified tissue, effectively debulking the lesion. Rotational and directional atherectomy have been associated with a variety of matters including distal embolization, poor flow, vessel dissection/perforation, and device issues such as burr entrapment and replacement [21]. Due to embolic issues, rotational atherectomy has been combined with aspiration in the Jetstream device (Boston Scientific, Marlborough MA).

Figure 5. A. Image of how the directional atherectomy device debulks plaque from the side of the catheter. *

Orbital Atherectomy:
Orbital atherectomy consists of a burr with an eccentrically attached crown that is diamond encrusted and rotates within the vessel at a variable radius. Instead of cutting head on as with rotational atherectomy or on the side as with directional atherectomy, orbital atherectomy uses an abrasive centrifugal action that breaks down calcified plaquel[22]. This mechanism of action is theorized to induce less vessel wall trauma and decrease risks of dissection and emboli. Diamondback 360, Predator 360, and Stealth 360 (Cardiovascular Systems, Saint Paul MN) are orbital atherectomy devices. Due to the rotating mechanism of action, caution should applied in vessels smaller than 2.5 cm due to increased risk of vessel dissection and perforation.

Laser Atherectomy:
Laser atherectomy uses energy in UV light to break down fibrous plaque. There have been multiple iterations of laser atherectomy devices that over the years that have increasingly transitioned to shorter wavelengths which allow for more debulking but at a lesser depth. The Excimer (Phillips, Netherlands) uses laser technology and works over a 0.014 wire and requires a 6 French sheath. The device comes in a variety of sizes and can be used in vessels greater than 2.0 mm. Due to UV light delivery being variable with calcifications, the manufacturer recommends against its use in heavily calcified vessels.

Image 2. 82 year old male with severe claudication. A. Digital subtraction image demonstrates multilevel stenotic disease of the distal superficial femoral and proximal popliteal arteries. B. Nav6© (Abbot, Chicago IL) filter was placed to protect against emboli. C. Jetstream© atherectomy was then performed. D. Digital subtraction image after atherectomy was performed with improvement but areas of residual disease. E. Digital subtraction image after 4 mm conventional angioplasty was performed. The lesion was then treated with 5mm drug coated angioplasty.



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